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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,020	03/11/2004	Bradley A. Saville	95772-1440	3924

20736 7590 01/08/2007  
MANELLI DENISON & SELTER  
2000 M STREET NW SUITE 700  
WASHINGTON, DC 20036-3307

EXAMINER
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ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1647

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/797,020		SAVILLE ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Marianne P. Allen		1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Oath/Declaration***

The petition granted 11/18/04 concerning non-signing inventor Mikhail I. Khavkine is noted.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 1-20 require an aqueous solution comprising a cross-linking agent and polymeric aldehyde species and active centre species.

Claims 1-20 require reducing the amount of both polymeric aldehyde species and other active centre species using a purifying agent.

The specification does not structurally identify any “active centre species” that are present in the aqueous solution or that are reduced or removed by treating any cross-linking agent with any purifying agent.

The examples disclose treating glutaraldehyde solutions with either activated charcoal or activated carbon. The amount of monomeric glutaraldehyde following activated charcoal treatment was slightly increased, 93% versus 91% when comparing Examples 3 and 2, respectively. This addresses the limitation of reducing the polymeric aldehyde species. However, the identity of other compounds meeting the limitation of “active centre species” and/or their reduction or removal is not disclosed. One of ordinary skill in the art would not know what compounds must be present in the aqueous solution nor what compounds to remove from the cross-linking agent as required by the claims.

Without knowing the particular compounds to reduce or remove, one of ordinary skill in the art would not have been able to extrapolate from glutaraldehyde as the cross-linking agent and activated carbon or activated charcoal as the purifying agent to other cross-linking agents or purifying agents embraced by the claims. One of ordinary skill in the art would not have known what aqueous solution comprising a cross-linking agent and polymeric aldehyde species and active centre species to use beyond that exemplified. The required “active centre species” must be considered implicitly present in the exemplified aqueous solutions in view of the specification disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-20 require reducing the amount of polymeric aldehyde species and “other active centre species.” While the specification discusses “active centre species” on page 2, lines 35-36, this disclosure does not define the meets and bounds of what compounds must be reduced or removed from the aqueous solution of cross-linking agent.

Claims 15-20 recite “any other group 3 hydrolase.” The specification does not define the meets and bounds of those hydrolases that are included or excluded by this phrase. The specification and prior art of record do not demonstrate that this would have been an art understood or known group of hydrolases.

Claims 1-20 are confusing because they are presented in Jepson format (see MPEP 2129 III). This format is viewed as an implied admission that the preamble steps are known in the prior art. However, for the reasons set forth above, the limitation “other active centre species” as recited in the preamble does not appear to have been known in the prior art. Clarification is requested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4, 6, 11, and 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Rembaum (U.S. Patent No. 4,369,226).

Rembaum discloses purifying an aqueous glutaraldehyde solution with activated carbon. It was free of polymer. The glutaraldehyde was then polymerized to form a support. Enzymes and other proteins may be immobilized to the support. See abstract, claims, Example 1, and column 17. Absent evidence to the contrary, the glutaraldehyde solution would inherently possess the recited active centre species and treatment with activated carbon would inherently reduce or remove these active centre species.

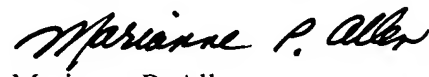
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Marianne P. Allen  
Primary Examiner  
Art Unit 1647

12/29/06

mpa